REMARKS

Claims 1, 2, 7 and 21-29 are pending in the application. By the above amendment, claim 1 has been amended. Further claims 22 - 29 have been withdrawn and canceled based on the finality of the restriction requirement. Further, claim 21 has been canceled. The specification and drawings have been amended. Applicant respectfully requests reconsideration of the claim rejections and specification and drawing objections based on the above amendments and the following remarks.

Election/Restriction Requirement:

Although Applicant respectfully disagrees with the restriction requirement, claims 22-29 have been canceled without prejudice as being withdrawn from consideration.

Drawing Objections:

The drawings were objected to for the reasons set forth on page 3 of the Office Action Applicants have made the changes to Fig. 2 as requested by Examiner, as indicated in the replacement sheet Fig. 2 annexed hereto, wherein the changes are highlighted in red marker. Accordingly, withdrawal of the objection is requested.

Specification Objection/Requirement for Information:

The specification was objected to for the reasons set forth on page 4 of the Office Action. Furthermore, Examiner has requested information under 37 CFR 1.105 regarding an inconsistency between the written description and data provided in Fig. 4, as well as an explanation for the exact replication of patient data provided in Figs. 3 and 4.

Applicant respectfully submits that the data illustrated in the originally filed Fig. 4 was inadvertently included in the specification. Such error was entirely inadvertent and was provided without any deceptive intent on the part of the Applicant. In fact, the correct data with respect to Autism was included in Applicant's United States Provisional Application No. 60/249,239, filed on November 16, 2000, which was fully incorporated in the specification by reference.

Accordingly, Applicant has submitted a new Fig. 4, which includes the Autism data presented in the above-incorporated provisional application, and has amended the specification consistent with the new Fig. 4. It is respectfully submitted that by virtue of the incorporation by reference of the provisional application, for example, the drawing and specification amendments do not constitute new matter.

If Examiner requires further information or explanation regarding Applicant's data, Applicant will provide such information.

Claim Objection

The objection of claim 21 is moot as claim 21 has been canceled without prejudice.

Claim Rejections - 35 U.S.C. § 112

(A) Claims 1, 2 and 7 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite due to the term PDD as recited in the claims. This rejection is essentially moot given that the claims have been amended to remove the term PDD.

However, Applicant respectfully submits that Applicant's specification clearly provides a definition for what is included in the class of disorders identified as PDDs. It is well known in the art that at the time the present application was filed, "PDDs" were a class of disorders

defined by both American and International diagnostic systems (i.e., the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) and World Health Organization: International Classification of Diseases, Tenth revision (ICD-10)). At the time of filing, the spectrum of PDDs were considered to include disorders such as Autism, Aspergers, ADD, and ADHD.

(B) Claims 1, 2, 7 and 21 stand rejected under 35 U.S.C. § 112, first paragraph, as being non-enabling for methods of determining if a person can develop PDD. More specifically, Examiner maintains that Applicant's specification is not enabling with respect to the presence of a plurality of different pathogens being predictive of PDDs. Although Applicant respectfully disagrees with this rejection on both law and fact, the rejection is essentially moot in view of the claim amendment. In particular, claim 1 now recites, inter alia, *identifying the presence of a plurality of different antigens in the stool sample as a biomarker that indicates that the individual has Autism.*

(C) Claims 1, 2 and 7 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement with respect to the definition of what constitutes PDD. Although Applicant respectfully disagrees with this rejection and Examiner's characterizations of Applicant's specification, the rejection is essentially moot in view of the claim amendments.

(D) Claims 1, 2, 7 and 21 stand rejected under 35 U.S.C. § 112, first paragraph, as being non-enabling for methods of diagnosing autism by detecting antigens of a plurality of other pathogens, other than those listed, for example, in Fig. 3 or on page 9 of Applicant's

specification. In other words, Examiner acknowledges that the claims are enabling with respect to diagnosing autism by detecting the presence of antigens from a plurality of pathogens as specifically listed, for example, on page 9 of Applicant's specification, but Examiner essentially contends that the application is not enabled for the full scope of the claimed invention directed to the detection of "any" plurality of pathogens being indicative of the identified disorder.

Applicant respectfully disagrees with this rejection. To the extent that Examiner's interpretation of the full scope of the claimed invention is based on "any pathogen" currently known or existing, it is respectfully submitted that such interpretation is not reasonable based on the teachings of Applicant's specification and based on knowledge of one of ordinary skill in the art. Clearly, at the very minimum, one of ordinary skill in the art would construe Applicant's specification as including any pathogen that is capable of living or thriving in the gastrointestinal tract of an individual. There are many known pathogens that cannot possibly live or exist in the gastrointestinal tract of an individual to environmental conditions, e.g., HCl, etc.

Further, although Applicant's specification recites exemplary pathogens that are capable of thriving in the gastrointestinal tract of an individual, there is simply nothing in Applicant's specification that Examiner could point to which would limit the scope of the invention to those specifically listed pathogens, as contended by Examiner. In fact, Applicant specifically lists pathogens, by way of example, i.e., "including, but not limited to" (see e.g., Page 9, lines 7-14; Page 11, lines 2-6; Page 14, lines 16-21). Clearly, at the very minimum, Applicant's specification teaches and suggests pathogens that can exist in the gastrointestinal tract of an individual.

Furthermore, to the extent that Examiner interprets Applicant's specification and claims as being directed to "specific sets of pathogens being associated with a particular disorder", it is respectfully submitted that such interpretation is unreasonably narrow, and not supported by Applicant's specification. Indeed, there is nothing in Applicant's specification that states or suggests that a "particular set of pathogens" is associated with a specific disorder. In fact, Figs. 2 and 3 clearly show that individuals having the same disorder, e.g., Parkinsons, ADD, ADHD, were found to have different sets of pathogens in the stools. Clearly, the teachings of Applicant's specification provides support for broadly claiming multiple pathogens, in general, and not simply a "particular set" of pathogens.

Furthermore, in the Office Action, Examiner has essentially ignored and not even addressed the statistical analyses set forth in Applicant's previously submitted Declaration under 37 CFR 1.132. In the Declaration, Applicant presented the results of various statistical tests to demonstrate the existence of a "reasonable correlation" between (i) the presence of a plurality of different antigens in a stool sample of an individual and (ii) the existence of a disorder such as Dysautonomia, Parkinson's disease, and PDDs, or the potential for the individual to develop such disorders.

Therefore, for at least the reasons given above, Applicant's specification is clearly enabling for pathogens other than those specifically listed in the specification.

(E) Claims 1, 2, 7 and 21 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth on pages 11-12 of the Office Action. Essentially, Examiner contends that Applicant has identified a number

of specific pathogens that are associated with PDDs or Autism, but that the teachings of the application identify only specific sets of pathogens associated with PDD disorders.

Applicant respectfully disagrees with this rejection both in law and fact. To begin, although the rejection is grounded on failure to satisfy the written description requirement, Examiner's analysis is not directed to "written description" but rather appears to be based on lack of enablement (which is redundant in view of previously discussed rejection). Indeed, Examiner contends on page 11 of the Office Action that "while the Applicant has demonstrated an association between certain PDDs and a number of specific pathogens, they have not established that these disorders may be associated with any combination of pathogens". It is respectfully submitted that such contention is not legally sufficient to support a rejection based on the "written description" requirement.

In assessing whether a specification satisfies the "written description" requirement under 35 U.S.C. 112, first paragraph, with respect to the claimed invention(s), the fundamental factual inquiry is whether the patent specification describes the claimed invention with *reasonable* clarity such that one of ordinary skill in the art can reasonably conclude that the inventor(s) had possession of the claimed invention as of the filing date of the specification. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using "such descriptive means as words, structures, figures, diagrams, etc., that fully set forth the claimed invention." *Lockwood v. American Airlines, Inc.* 107 F.3d 1565, 1572 (Fed. Cir. 1997). "If a person of ordinary skill in the art would have understood the inventor to have been in possession

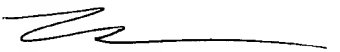
of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description is met." *In re Alton*, 76 F.3d at 1175 (see also *Vas-Cath*, 935 F.2d at 1563).

Here, Applicant's specification is replete with sufficient "written description" that would lead one of ordinary skill in the art to reasonably conclude that the Applicant had possession of the claimed inventions, e.g., claim 1, for at least the same reasons given above in section (E) of this Amendment. Again, it is respectfully submitted that Examiner's interpretation or characterization of Applicant's specification being limited with respect to the pathogens is improper, as there is nothing in Applicant's specification that could be construed as limiting the claimed inventions to a particular set of pathogens being correlated to disorders..

Therefore, based on the above, the withdrawal of the claim rejections under 35 U.S.C. §112, first and second paragraph, is respectfully requested.

In view of the foregoing remarks and amendments, it is respectfully submitted that all the claims now pending in the application are in condition for allowance. Early and favorable reconsideration of the case is respectfully requested.

Respectfully submitted,



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